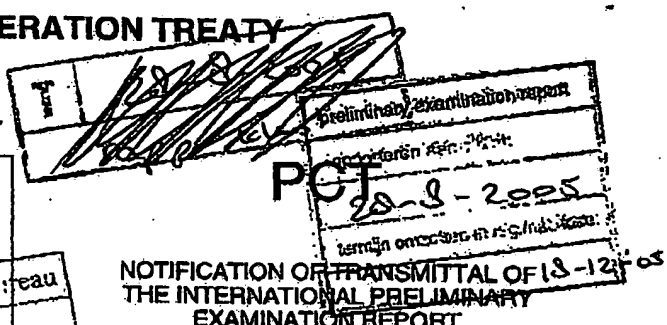
PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY



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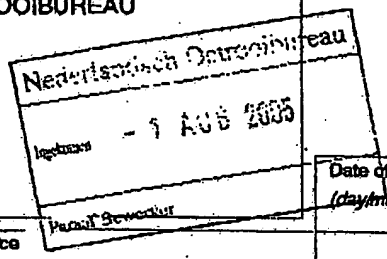

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	28.07.2005
Applicant's or agent's file reference: P209264PCT DBO/do	IMPORTANT NOTIFICATION

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NL 03/00445	18.06.2003	18.06.2003

Applicant
N.V. NUTRICIA et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Nielsen-Hannerup, A Tel. +49 89 2399-7739

Form PCT/IPEA/416 (January 2004)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P209264PCT DBO/do	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/NL 03/00445	International filing date *(day/month/year)* 18.06.2003	Priority date *(day/month/year)* 18.06.2003
International Patent Classification (IPC) or both national classification and IPC A23L2/40		
Applicant N.V. NUTRICIA et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16.02.2005	28.07.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax +49 89 2399 - 4465	Authorized Officer Smeets, D Telephone No. +49 89 2399-7492

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/NL 03/00445

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-22 as originally filed

Claims, Numbers

1-16 received on 16.06.2005 with letter of 16.06.2005

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-16
	No:	Claims	
Inventive step (IS)	Yes:	Claims	3,10-14
	No:	Claims	1-2,4-9,15, 16
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-A-4414198
D2: US-B1-6290997
D3: US-A-5476675
D4: US-A-1945963
D5: FR-A-2733420
D6: EP-A-0455475

1 Novelty - Article 33(1) and (2) PCT

The subject-matter of independent claims 1,12, 13 and 15 is novel as the subject-matter of said claims is not disclosed in any of the prior art documents.
Claims 2-11, 14 and 16 are dependent on claims 1,12,13 and 15 and as such also meet the requirements of the PCT with respect to novelty.

2 Inventive step - Article 33(1) and (3) PCT

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 and 15 does not involve an inventive step in the sense of Article 33(3) PCT.

D4 teaches about improved pectin preparations capable of being readily and rapidly dispersed in aqueous media without the formation of lumps or undesirable frothing. Warm or hot aqueous media are preferably employed since they give more satisfactory results.

Adding oligosaccharides to increase the SCFA content is a straightforward possibility that will be done where the circumstances make it desirable.
Thus, the subject-matter of independent claims 1 and 15 is obvious for the skilled person.

Combining pectin, oligosaccharides and calcium in order to increase the bioavailability of the calcium in the fiber product is not derivable from the available prior art documents.
Therefore, the subject-matter of claims 3, 10-12, 13 and 14 is considered to involve an inventive step.

3 The following observations are also made:

3.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D4,D6 is not mentioned in the description, nor are these documents identified therein.

3.2 There is a typing error in claim 14; said claim should be dependent on claim 13.

CLAIMS

1. A process for preparing a hot liquid fiber product for enteral administration, comprising admixing:
   a. a serving of a reconstitutable composition comprising
      (i) between 0.1 gram and 75 grams ~~fibre pectin~~; ~~and~~
      (ii) indigestible oligosaccharide with a degree of polymerization exceeding 2 and below 60 monose units; and
      (iii) an effervescent system;
      and
   b. a liquid with a temperature that exceeds 35°C

2. The process according to claim 1, wherein the indigestible oligosaccharide is selected from the group consisting of fructans, fructooligosaccharides, indigestible dextrins galactooligosaccharides (including transgalactooligosaccharides), xylooligosaccharides, soybean oligosaccharides, arabinooligosaccharides, glucooligosaccharides, mannooligosaccharides, fucooligosaccharides and mixtures thereof. ~~The process according to claim 1, wherein the fiber has an average molecular weight of at least 400 Da, preferably at least 5000 Da.~~

3. The process according to claim 1 or 2, wherein the reconstitutable composition further comprises a calcium salt.

4. The process according any one of the preceding claims, wherein the liquid has a volume of between 50 and 1000 ml.

5. The process according to any one of the preceding claims, wherein the fiber is ~~selected from the group consisting of~~ low-methoxylated pectin ~~and alginate~~.

6. The process according to any one of the preceding claims, wherein the effervescent system contains at least one base that liberates carbon dioxide selected from the group consisting of sodium carbonate, potassium carbonate, sodium bicarbonate,

potassium bicarbonate, calcium bicarbonates, ammonium bicarbonate and sodium glycine carbonate.

7. The process according to claim 6, further comprising an acidic ingredient selected from the group consisting of as citric, tartaric, adipic, fumaric, malic, lactic, acetic, maleic and benzoic acids, and phosphates.

8. The process according to any one of the preceding claims, wherein the reconstitutable composition further comprises NaCl and/or glutamate.

9. The process according to any one of the preceding claims, wherein the resulting liquid fiber product has a pH above 4.

10. The process according to any one of the preceding claims, wherein the reconstitutable composition contains a calcium salt with a solubility below 0.15 g per 100 ml water at 20°C and pH 7 which provides more than 0.05 gram dissolved calcium per 100 ml water at a pH below 4 and a temperature of 37°C, and the resulting liquid product (i) has a viscosity below about 100 mPas, and (ii) exhibits a viscosity above about 250 mPas when it is acidified to pH 3.

11. A hot liquid fiber product with a viscosity below 100 mPas, a pH that exceeds 4 and a temperature of at least 35°C, prepared with the process according to claim 10.

12. A hot liquid fiber product with a viscosity below 100 mPas, a temperature of at least 35°C and a viscosity of at least 250 mPas when it is acidified to pH 3, said composition comprising (i) a calcium salt with a solubility below 0.15 g per 100 ml water at 20°C and pH 7 which provides more than 0.05 gram dissolved calcium per 100 ml water at a pH below 4 and a temperature of 37°C, (ii) per serving between 0.1 gram and 75 grams fiber, (iii) indigestible oligosaccharide with a degree of polymerization exceeding 2 and below 60 monose units.

13. Use of fiber in the manufacture of composition for use in a method for the treatment and/or prevention of a diet responsive condition in a monogastric mammal, said

method comprising enterally administering to the mammal the composition of claim 11 or 12.

14. Use according to claim 14, wherein the diet responsive condition is overweight.

15. A packaged reconstitutable composition which bears instructions to mix one or more servings of the reconstitutable composition with a liquid having a temperature above 35°C, said composition comprising per serving:

(i) between 0.1 gram and 75 grams pectin ~~fiber~~;

(ii) indigestible oligosaccharide with a degree of polymerization exceeding 2 and below 60 monose units; and

(iii) an effervescent system

16. The packaged composition according to claim 15, wherein the composition comprises per serving:

(i) between 0.5 and 15 g low methoxylated pectin and/or alginate;

(ii) between 0.01 and 25 grams base that liberates carbon dioxide, preferably selected from the group consisting of sodium carbonate, potassium carbonate, calcium carbonate, sodium bicarbonate, potassium bicarbonate, calcium bicarbonates, ammonium bicarbonate and sodium glycine carbonate;

(iii) between 0.025 and 5 grams acidic ingredient, preferably selected from the group consisting of citric, tartaric, adipic, fumaric, malic acids, lactic, acetic, malcic and benzoic acids; and phosphates and

(iv) between 0.05 and 5 grams calcium.

~~17. The composition according to claim 15 or 16, further comprising indigestible oligosaccharide.~~